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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09/456,278	12/07/1999	Jesus Miranda	P24,540 USA	6233

7590 07/08/2003

SYNNESTVEDT & LECHNER LLP
ATTN: PATRICK J. KELLY, Ph.D.
2600 ARAMARK TOWER
1101 MARKET STREET
PHILADELPHIA, PA 19107-2950

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/456,278	MIRANDA ET AL.
	Examiner	Art Unit
	Isis Ghali	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 December 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *2,4,5 and 8-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6,7 and 27-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' associate power of attorney, request under 1.114, request for extension of time and IDS, all filed 10/07/2002; and amendment B, filed 12/30/2002.

Claim 28-38 has been added per applicants' amendment B, in Paper No. 14.

Claims 2, 4, 5, 8-26 are withdrawn from consideration being drawn to an invention nonelected with traverse in Paper No. 5.

Claims 1, 3, 6, 7, and 27-38 are included in the prosecution.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/07/2002 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 6, 7, 27-31, 34, 35, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,004, 610 ('610) in view of US 5,914,282 ('282).

Applicants' claims 1 and 27 read as follows:

A transdermal patch comprising the following layers:

- An impermeable backing layer,
- Silicone adhesive layer containing the drug,

- Acrylic adhesive layer, and
- Removable release liner.

US '610 teaches a rate-controlled nicotine (volatile drug) delivery system comprising:

- An impermeable backing,
- Nicotine reservoir,
- Nicotine release adhesive layer, and
- A release liner. (Abstract; col.2, lines 60-65; col.3, lines 37-43).

The device delivers nicotine in an amount of 0.2 to 4.0 mg/hr (col.5, line 37-39). The reservoir comprises silicone adhesive and nicotine (col. 7, Example I, lines 51-55). The drug reservoir contains 20 or 25 weight percent of nicotine, claims 34 and 37 (Example I, col.7, lines 66-67). The reference teaches that the thickness of the adhesive layer is selected so that at least 50-75% of the initial equilibrated nicotine loading is in the reservoir layer (col.5, lines 16-20), and example V, col.9, lines 20-24, discloses that the weight percent of the adhesive after equilibration is from 8-14 %, claim 35. The thickness of the silicone adhesive layer containing the nicotine after drying (solid) is 0.05 mm, i.e. 50 micron, claim 29 (Example I, col.7, lines 67-68). The release liner is siliconized, claim 6 (col.8, line 68-col.9, line 2). The reference teaches that the thickness of the adhesive layer is selected such that the adhesive does not constitute a significant permeation barrier to the passage of the drug (col7, lines 24-27).

However, the US '610 does not teach the adhesive layer as acrylic adhesive as in component (c) of claims 1 and 27, claims 28 and 30, or the components of the acrylic

adhesive as claimed in claims 7 and 38. The does not teach the thickness of the adhesive layer as in claim 31.

One having ordinary skill in the art would have been motivated to adjust the thickness of the adhesive layer motivated by the teaching of US '610 that the thickness of the adhesive layer is selected so that at least 50-75% of the initial equilibrated nicotine loading is in the reservoir layer and also the teaching that the thickness of the adhesive layer is selected such that the adhesive does not constitute a significant permeation barrier to the passage of the drug, with reasonable expectation of success of the delivered transdermal device to provide nicotine to the skin in a controlled manner.

US '282 teaches a pressure sensitive adhesive useful for medical dressings and has the advantages of ease of manufacture, excellent safety history profile, high shear strength, low coast and chemical stability (abstract; col.1, lines 7-12; col.3, lines 48-52). The adhesive comprises a blend of two components at the ratio of 10:90 to 90:10, and the first component comprising iso octyl acrylate and ethylhexyl acrylate (col.3, lines 35, 63-64; col.7, lines 17-20).

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to replace the adhesive layer disclosed by US '610 by the acrylic adhesive layer disclosed in US '282, motivated by the teaching of US '282 that the disclosed acrylic pressure sensitive adhesive has the advantages of ease of manufacture, excellent safety history profile, high shear strength, low coast and

chemical stability, with reasonable expectation of having a drug delivery device that is safe and stable for treating drug dependency with success.

5. Claims 3, 32, 33, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '610 in view of US '282 as applied to claims 1, 6, 7, 27-31, 34, 35, 37 and 38 above, and further in view of US 5,316,759 ('759).

The teachings of US '610 in view of US '282 are discussed above.

However, the references in combination do not teach the drug as a combination of nicotine and mecamylamine as claimed in claims 3, 32 and 33, or that the amount of the drug is sufficient to provide administration of the drug for a period up to about 72 hours as claimed in claim 36.

US '759 is teaching the transdermal drug delivery of nicotine and mecamylamine combined in a single dose in the form of a patch, claims 32 and 33, so that the administration of the drug and its antagonist together in the same patch will not allow the drug user or abuser to separate the desired portion of the composition, i.e. the drug, from the antagonist. The patch comprises an impermeable backing; reservoir containing silicone polymer matrix and the drugs; and releasable liner. The patch provides a steady rate of delivery of 1-4 mg per hour of nicotine and 0.5-1 mg per hour of mecamylamine, same amounts claimed in claim 3. See the abstract; col.3, lines 26-30; col.4, col.5, lines 6-9; col.6, lines 50-64; col.8, lines 6-8, 29-32, 43-50, 65-67; col.9, lines 19-41.

It is expected to the transdermal patch disclosed by US '759 that contains the same amounts of the nicotine and mecamylamine as that claimed by applicant in claim

3 to provide administration of the drug for a period up to about 72 hours as claimed in claim 36.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a transdermal patch for administering volatile drugs comprising backing, silicone adhesive layer containing the drug, acrylic adhesive layer and removable release liner as disclosed by US '610 in view of US '282, and replace the nicotine by both nicotine and its antagonist mecamylamine in the drug containing layer as taught by US '759, motivated by the teaching of US '759 that the administration of the drug and its antagonist together in the same patch will not allow the drug user or abuser to separate the desired portion of the composition, i.e. the drug, from the antagonist, with reasonable expectation of treating patients suffering from nicotine dependency using the delivered patch with success.

Response to Arguments

6. Applicant's arguments with respect to claims 1, 3, 6, 7, 27 have been considered but are moot in view of the new ground(s) of rejection.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

Isis Ghali
Examiner
Art Unit 1615